Course Purpose:
In this course, students will learn about the compounding of non-sterile and sterile pharmaceutical preparations. Included in the topics are the history, standards, regulations, and quality assurance of compounding operations along with the materials and techniques for compounding high quality preparations of a variety of dosage forms for a variety of routes of drug administration.

Course Faculty and Office Hours
Course Coordinator:
Cary Mobley, R.Ph., Ph.D.
Email: mobley@cop.ufl.edu  Office: HPNP 1315  Phone: 352-273-6282

Office Hours:
By appointment (mobley@cop.ufl.edu)

Instructors:

<table>
<thead>
<tr>
<th>Instructor</th>
<th>Title/Position</th>
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<tbody>
<tr>
<td>Cary Mobley, R.Ph., Ph.D.</td>
<td>Clinical Associate Professor of Pharmaceutics</td>
</tr>
<tr>
<td>Janet Schmittgen, R.Ph.</td>
<td>Adjunct Clinical Instructor</td>
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<tr>
<td>Justin Giaquinta, Pharm.D.</td>
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<tr>
<td>Leonardo Esperón, Pharm.D.</td>
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<tr>
<td>Ivett Hernandez, Pharm.D.</td>
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<tr>
<td>Alissa Voils, Pharm.D., MSHA</td>
<td>Assistant Director, Inpatient Pharmacy Services Department of Pharmacy 1 UF Health Shands Hospital</td>
</tr>
<tr>
<td>Tim Hoggard, R.Ph.</td>
<td>Sterile Compounding Specialist, UF Health Shands Hospital.</td>
</tr>
<tr>
<td>Amir Y. Kamel, Pharm.D., BCNSP</td>
<td>Clinical Pharmacy Specialist, Nutrition Support / Critical Care. UF Health Shands Hospital</td>
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<tr>
<td>Denise M. Klinker, Pharm.D., M.B.A.</td>
<td>Director of Experiential Programs, Clinical Assistant Professor Pharmacotherapy and Translational Research</td>
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<tr>
<td>Randy C. Hatton, Pharm.D., FCCP, BCPS</td>
<td>Clinical Professor Pharmacotherapy and Translational Research</td>
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<tr>
<td>Anzeela M. Schentrup, Pharm.D., Ph.D., BCPS</td>
<td>Clinical Assistant Professor Pharmacotherapy and Translational Research</td>
</tr>
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</table>

Directions for Contacting Course Faculty:
Please feel free to contact the course coordinator, Cary Mobley, via email (mobley@cop.ufl.edu). Please put “PHA5104” in the email subject, and please indicate which campus you attend in your email signature. Emails will be returned as soon as possible.

Place and Time of Class Session
Lectures in Gainesville in G312: Monday 1:55-2:45 and Wednesday 11:45-12:35 for Live Lectures – Please see Course Schedule
How This Course Relates to the Learning Outcomes You Will Achieve in the Pharm.D. Program:

This course prepares the Pharm.D. student to accomplish the following abilities and the related Student Learning Outcomes (SLOs) upon graduation:

1. Develop, integrate, and apply knowledge from the foundational disciplines (i.e., pharmaceutical, social/behavioral/administrative, and clinical sciences) to evaluate the scientific literature, explain drug action, assess and solve therapeutic problems, and advance population health and patient-centered care. (Foundational)
2. Provide patient-centered care as the medication expert (collect and interpret evidence, prioritize patient needs, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities). (Foundational)
3. Manage patient healthcare needs using human, financial, technological, and physical resources to optimize the safety and efficacy of medication use systems. (Foundational)

Course Objectives

Upon completion of this course, the student will be able to:

1. Define compounding.
2. Describe the history and purposes of pharmacy compounding.
3. Distinguish pharmacy compounding from pharmaceutical manufacturing.
4. Become knowledgeable of USP and other standards important for the practice of non-sterile and sterile compounding.
5. Give an overview of the regulation of compounding pharmacy.
6. Determine beyond-use dates for compounded preparations.
7. Describe the purposes, selection criteria, and proper usage of compounding equipment and ingredients.
8. Describe the general guidelines for preparing, packaging, and labeling compounded non-sterile and sterile drug preparations.
9. Perform calculations required to prepare and assess compounded non-sterile and sterile preparations.
10. Describe the concepts, principles, and common techniques for compounded non-sterile and sterile preparations.
11. Describe essential concepts and methods of evaluating the stability and compatibility of compounded non-sterile and sterile preparations.
12. Describe essential concepts of engineering controls for sterile compounding.
13. Describe aseptic techniques critical for sterile compounding.
14. Describe the proper handling of hazardous chemicals used in sterile compounding.
15. Describe essential concepts and techniques for the preparation of parenteral nutrition preparations.
16. Describe special considerations for the intravenous drug therapy in infants and children.
17. Describe methods of quality assurance and quality control of compounded non-sterile and sterile preparations.
18. Describe methods of final product verification of compounded sterile preparations.
Course Structure & Outline

Course Structure.

1. This is a lecture-based course wherein lectures are delivered live or pre-recorded in Gainesville for viewing and listening by students at all College of Pharmacy sites.
2. Lecture handouts for the first two modules are written in a consistent, outline-based manner and are designed to be succinct consolidations of essential concepts and facts. Lecture handout for modules 3 and 4 will be pdf versions of PowerPoint presentations.
3. Web Page Lectures: Lectures by Dr. Mobley are delivered as web pages with hyperlinks to explanations, facts, definitions, illustrations, examples, and other related content from other lectures and from the Internet. These web-page versions of the lectures are made available online for student self-usage approximately one-week before each exam.
4. PowerPoint Lectures: Lectures by faculty other than Dr. Mobley are delivered primarily as PowerPoint lectures.
5. Practice Assessments: Non-mandatory practice assessments will be made available in ELS to help students self-assess their understanding of course concepts and facts.
6. Required Reading Assignments: Periodic supplemental reading assignments from the course texts and the Internet will be required to increase the comprehensiveness and clarity of course topics. These assignments are chosen in consideration of their concision and clarity. Material from required reading assignments will be material for exams.
7. Recommended Reading Assignments: For each major course topic, supplemental reading assignments will be recommended. This material will not be required for exams.
8. Discussion Boards: Two types of discussion boards made in ELS:
   a. Student-to-Student Discussion Board – an unmonitored discussion board for students to communicate with each other
   b. Exam-Specific Discussion Board – a discussion board monitored by course instructors dedicate to help students clarify course material related to specific upcoming exams

Course Outline/Activities. See the Course Schedule in at the end of this document.

Required Course Materials

A. Required Texts:


   (This text can be purchased directly from the publisher at 25% off and free shipping. Please use the following link and then enter the code: OCHOAUFL15

B. Simple Calculators - Calculators allowing NO text input, graphing, or programming
Active Learning

For all learning experiences in this course, including reading assignments and lectures, students are expected to be effortful and actively engage their minds in the learning process, striving to grasp the meaning and relevance of all presented concepts and facts, with a goal of integrating new knowledge with existing knowledge. Students should strive to discover deficiencies in their understanding, and attempt to resolve those deficiencies by any of several means, including through their own research (a recommended first-step) and through consultation with course instructors and fellow student-pharmacists.

1. Lecture Viewing – Watching and listening to lectures are considered active processes in this course. As with other audiovisual-based forms of communication, the recipients are expected to actively engage their minds to understand the material and integrate it with their existing knowledge base. Instructors must continuously strive to create and deliver lectures in a manner that stimulates the engagement and aids the integration.

2. Self-Paced Web-Based Lecture Review – When made available, students are welcome to navigate the lecture material from the first two modules on their own, exploring hyperlinks to a variety of inter-related facts and concepts.

3. Reading Assignments – As with lectures, students are expected to actively engage in their understanding of the ideas communicated in reading assignments.

4. Practice Assessments and Discussion Boards in ELS - It is recommended that students take advantage of the voluntary practice assessments and discussion boards to help self-assess learning needs.

Student Evaluation & Grading

Evaluation Methods

Students will be evaluated using four, non-cumulative exams, each worth 25% of the final grade:
Exam 1 – Sep. 21
Exam 2 – Oct. 19
Exam 3 – Nov. 15
Exam 4 – Dec. 14

Grading Scale

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<th>A</th>
<th>A-</th>
<th>B+</th>
<th>B</th>
<th>B-</th>
<th>C+</th>
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Class Attendance Policy

Attendance is not required for lectures.
Exam Policy

Exam Rules

1. Students must arrive and be seated promptly to be eligible to take the exam. Penalties for tardiness:
   One point per minute may be deducted for students arriving late to an exam. Students who arrive
   more than 10 minutes late to an exam are not eligible to take the exam and must contact the course
   coordinator within 24 hours of the exam to arrange for a makeup exam that may be offered,
   depending on the circumstances surrounding the tardiness.

2. No talking or other disruptive behavior during the distribution or taking of the exam.

3. No calculators allowing text input, graphing, or programming will be allowed to be used in an exam.
   Use of such calculators will be considered evidence of academic dishonesty

4. No sharing of calculators.

5. Nonessential materials (e.g., books, coats, notes, purses, etc.) are NOT allowed at the student's desk
   during examination periods. Please leave all nonessential materials outside of or in the front of the
   examination room.

6. Other exam rules may be instituted during the progression of the course.

7. Exams will be administered using ExamSoft. Once the exam commences, students may not leave the
   room (e.g., for a bathroom break) without first submitting the exam and showing evidence of
   completion to the proctors. Once the exam is submitted, the examination period for the student is
   considered concluded.

Failure to follow exam rules may be considered as evidence of academic dishonesty.

Review of Exams by Students

Exams will be administered using ExamSoft. The exam includes a 10 minute review immediately after
the exam is submitted. There is no exam rebuttal process no additional points will be awarded based on
students contesting a question. However, aided with statistical analysis, exam questions will be
reviewed and may be discarded if the question is deemed to be erroneous or poorly written.

Makeup Exam Policy

Makeup exams are given only under special circumstances. If the student is unable to take a scheduled
examination, the course coordinator must be notified before the examination. In addition, a written
letter of explanation, requesting that the absence from the exam be excused, must be presented before
the exam or immediately afterwards. An excused absence is allowable when: 1) the student is
hospitalized and/or has been advised by a licensed medical practitioner or hospital not to attend the
exam, or 2) if there is a documented death of an immediate family member. All excused absences will be
considered on an individual basis by the course coordinator. Depending on the decision, a
comprehensive exam may be given, which will contain material from all previous exams. The questions
on the makeup exam may be in the form of essay, short answer, or multiple-choice. With the exception
of highly extenuating circumstances, failure to follow the prescribed procedures or failure to attend the
announced comprehensive examination will result in a grade of zero for that exam. A request for an
"excused absence" does not guarantee acceptance. No precedence can be drawn from any courses in
the College of Pharmacy or any other college within University of Florida.

Policy on Old Quizzes and Assignments

Old exams are not provided, but Self-Assessments in ELS will include exam-like practice questions.

Assignment Deadlines

N/A
General College of Pharmacy Course Policies
The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

Complaints

Should you have any complaints with your experience in this course please visit:

http://www.distancelearning.ufl.edu/student-complaints to submit a complaint.
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<th>Topic</th>
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<tr>
<td>Aug. 22</td>
<td>Course Overview / History of Compounding*</td>
<td>Mobley/Schmittgen</td>
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<tr>
<td>Aug. 24</td>
<td>Overview Compounding Practice and Standards</td>
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<td>Aug. 29</td>
<td>Stability and Beyond-Use Dating of Non-Sterile Preparations (Ch. 4 and 37)</td>
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<td>Aug. 31</td>
<td>Compounding Equipment and Ingredients (Ch. 13 and 14)</td>
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<td>Sep. 5</td>
<td>Labor Day – No Class</td>
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<td>Sep. 7</td>
<td>Pharmaceutical Excipients (Part 4)</td>
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<td>Sep. 12</td>
<td>General Guidelines for Preparing and Labeling Compounded Drug Preparations (Ch. 2 and 12)</td>
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<td>Sep. 14</td>
<td>Review of Calculations</td>
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<td>Sep. 19</td>
<td>Powders (Ch. 25)</td>
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<td>Module 1 Exam – Sep. 21&lt;sup&gt;st&lt;/sup&gt;</td>
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<td>Capsules, Lozenges, and Other Solid Oral Dosage Forms (Ch. 26)</td>
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<td>Sep. 28</td>
<td>Solutions and Emulsions (Ch. 27 and 29)*</td>
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<td>Oct. 3</td>
<td>Suspensions (Ch. 28)</td>
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<td>Oct. 5</td>
<td>Semisolids - Part 1 (Ch. 23 and 30)</td>
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<td>Oct. 10</td>
<td>Semisolids - Part 2 (Ch. 30)</td>
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<td>Oct. 12</td>
<td>Suppositories (Ch. 24 and 31)</td>
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<td>Oct. 17</td>
<td>Overview of Veterinary Compounding (Ch. 36)</td>
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<td>Chapter 1: Intro to Parenterals</td>
<td>Voils*</td>
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<td>Chapter 2: Supplies and Equipment</td>
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<td>Chapter 3: Calculations for Parenterals</td>
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<td>Nov. 2</td>
<td>Chapter 4: Microbiological Considerations in Parenteral Compounding</td>
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<td>Chapter 5: Primary and Secondary Engineering Controls</td>
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<td>Chapter 6: Aseptic Technique &amp; Compounding Manipulations</td>
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<td>Chapter 7: Principles of Compatibility and Stability</td>
<td>Giacquinta*</td>
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<td>How to Evaluate Literature on Stability and Compatibility</td>
<td>Hatton*</td>
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<td>Nov. 21</td>
<td>Chapter 8: Preparation of Hazardous Drugs for Parenteral Use</td>
<td>Esperón*</td>
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<td>Chapter 9: Multiple Product Preparations for Parenteral Nutrition</td>
<td>Kamel</td>
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<td>Nov. 30</td>
<td>Chapter 10: Considerations for Intravenous Drug Therapy in Infants and Children</td>
<td>Hernandez*</td>
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<td>Dec. 5</td>
<td>Chapter 11: Quality Assurance, Quality Control for Sterile Compounding and Final Product Verification</td>
<td>Klinker*</td>
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<td>Dec. 12</td>
<td>Finals Week</td>
<td>Module 4 Exam – Dec. 14&lt;sup&gt;th&lt;/sup&gt;</td>
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* Lectures that will be pre-recorded, i.e. no live session